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EXAMINER	
SINGH, SATYENDRA K	
ART UNIT	**PAPER NUMBER**
1657	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,987	SIX ET AL.	
	Examiner	Art Unit	
	Satyendra K. Singh	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 8-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 8-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 December 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response (and amendments to claims) filed with the office on February 6th 2007 is duly acknowledged.

Claim 7 has been cancelled by applicant's current amendments to the claims.

Claims 1-6 and 8-15 are examined on their merits in this office action.

This is a **new ground of rejection** necessitated by applicant's amendments to the pending claims.

Election/Restrictions

The election of species (as previously set forth by the examiner and elected by applicants as Eudragit E100) has been **withdrawn** and all the species have been rejoined and examined for their patentability.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 (as currently amended) is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains **subject matter which was not described** in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 recites the newly added limitation "wherein said first polymer and said second polymer are present in a ratio of **about** 70:30 to **about** 80:20". The disclosure

provided by applicants in the original claim 7 ("wherein a Eudragit E100/PVPVA 64 ration varies between 70/30 and 80/20"), does not provide an explicit support for the claim amendment as currently presented by applicants. In addition, applicant's remarks (filed with the office on February 6th 2007; see pages 4 and 5, 1st paragraphs, in particular) do not point to a proper support for such amendments to the claim 1. In addition, such a ratio for the solid dispersion as claimed in instant claim 8 (i.e. Hydroxy-propyl methylcellulose and a copolymer of vinylpyrrolidone and vinylacetate, in combination) is not disclosed and supported by the instant disclosure provided by applicants.

Since, the claimed invention is not fully supported by the instant disclosure, either in the narrative or generic or in the examples or in the original claims provided by applicants, the claimed limitation constitutes a new matter situation. Appropriate explanation/correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-6 and 8-15 are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg et al (WO 02/11694 A2; IDS) in view of Baert et al (WO 97/44014; IDS) or Jung et al (WO 99/33467; IDS).

Claims are generally drawn to a solid dispersion (i.e. a composition) comprising a poorly soluble bioactive compound dispersed in a polymeric matrix that comprises a first polymer that allows a homogeneous or molecular dispersion of the bioactive compound in the polymer matrix, and a second polymer that has a dissolution profile associated with the creation of a micro-environment enhancing the dissolution of the bioactive compound in an aqueous environment, wherein said first polymer and said second polymer are present in a ratio of about 70:30 to about 80:20 (see instant claim 1 as amended).

Rosenberg et al (IDS) teach antifungal compositions and dosage forms (such as solid dispersions suitable for application in the oral cavity) comprising a poorly bioavailable pharmaceutical active ingredient (such as itraconazole; see Rosenberg et al, abstract, page 2, lines 10-43, and claims, in particular) dispersed in a pharmaceutically acceptable matrix that can comprise of polymers such as hydroxyalkyl alkylcellulose (i.e. HPMC, hydroxyl-propyl methylcellulose), or Eudragit ™ (a cationic polymer based on dimethylaminoethyl methacrylate and neutral methacrylic esters), or homo- and copolymers of n-vinylpyrrolidone/vinyl acetate (similar to the polymeric matrix, PVPVA 64 or a copolymer of vinylpyrrolidone and vinylacetate, as claimed; see Rosenberg et al, page 3, lines 6-17, in particular). Rosenberg et al teach the solid dispersions comprising a class II drug, itraconazole and a combination of polymer matrices such as n-vinylpyrrolidone/vinyl acetate copolymer and hydroxypropyl cellulose

(HPC) that provide homogeneous dispersion and enhanced solubility under aqueous conditions of the oral cavity (see Rosenberg et al, page 7, examples 1-3; page 6, lines 14-24, in particular).

However, although suggested by the prior art (see Rosenberg et al, discussion supra), solid dispersions comprising a poorly soluble bioactive compound dispersed in a combination of polymer matrices as claimed in instant claims 6 (i.e. a cationic polymer based on dimethylaminoethyl methacrylate and neutral methacrylic esters or Eudragit E100, and a copolymer of vinylpyrrolidone and vinylacetate or PVPVA64) and claim 8 (i.e. **HPMC** and a copolymer of vinylpyrrolidone and vinylacetate) are not explicitly taught by the referenced invention of Rosenberg et al.

Baert et al (IDS) teach antifungal compositions in the form of solid dispersions having improved bioavailability in an aqueous environment such as gastric fluid (see Baert et al, abstract, page 12-13, examples 1-5, and claims, in particular), wherein the polymer matrix comprises a polymer having a stabilizing effect on the bioactive compound (such as antifungal drug, itraconazole) in solution (see page 4, 2nd paragraph, in particular), wherein the polymer allowing enhanced dissolution of the bioactive compound in an aqueous environment is hydroxypropyl methylcellulose (see Baert et al, page 12, in particular), wherein the polymer allowing a homogeneous dispersion is crospovidone (a crosslinked polyvinylpyrrolidone, PVP, i.e. a derivative of PVP, functional equivalent to a copolymer of vinylpyrrolidone and vinylacetate or PVPVA64 as claimed in the instant invention; see Baert et al, page 10, 3rd and last paragraph, in particular), wherein one or more polymer matrices comprise HPMC and

crospovidone. The limitations of claims 9 and 10 are disclosed by the referenced invention as Baert et al teach solid dispersions comprising polymer matrix that enhance bioavailability of an orally administered bioactive compound, such as a class II drug (see the disclosure provided by the applicants, page 3, lines 16-18 of the instant specification), itraconazole/saperconazole (see Baert et al, page 10, in particular). The limitations of instant claims 14 and 15 (wherein the solid dispersions are prepared by extrusion or spray drying processes; product by process claims) are also met by the solid dispersions comprising itraconazole and polymer matrices such as HPMC and crospovidone (see Baert, discussion supra) that provide enhanced bioavailability to the antifungal drug when ingested orally. Thus the teachings of Baert et al, as discussed supra, disclose a solid dispersion comprising a bioactive, antifungal compound, itraconazole and HPMC (hydroxypropyl methylcellulose) in combination with crospovidone (a crosslinked polymer of polyvinylpyrrolidone, i.e. a functional equivalent) that are suitable for enteric compositions that are administered orally.

Jung et al (IDS) teach method and composition (solid dispersions) of an oral preparation of itraconazole comprising aminoalkyl methacrylate copolymer (i.e. Eudragit E; see abstract, examples 1-7, tables 3-5, and claims, in particular) that is suitable for oral ingestion and antifungal treatment. Jung et al also suggest the use of other polymer matrices in combination with Eudragit, such as crospovidone (as diluent; see Jung et al, page 8, 3rd paragraph, in particular).

It would have been obvious to a person of ordinary skill in the art at the time this invention was made to modify the composition (i.e. solid dispersions) taught by

Rosenberg et al such that the solid dispersions comprise of the poorly bioactive compound in two different polymeric matrices in combination with n-vinylpyrrolidone/vinyl acetate copolymer, such as HPMC or Eudragit, as explicitly suggested by the disclosures of Baert et al or Jung et al.

One of ordinary skill in the art would have been motivated at the time of invention to make such substitutions in the composition or solid dispersions of Rosenberg et al (i.e. using HPMC ,or a cationic polymer based on dimethylaminoethyl methacrylate and neutral methacrylic esters such as Eudragit E as polymer matrices) in order to obtain resulting composition comprising a bioactive agent of class II or class IV (in combination, such as itraconazole dispersed in a polymer matrix such as a copolymer of polyvinylpyrrolidone) as suggested by the references (Baert et al, or Jung et al) with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

The limitation "wherein said first polymer and said second polymer are present in a ratio of **about 70:30 to about 80:20**, would have been a matter of routine optimization to a person of ordinary skill in the art at the time this invention was made as evident by the fact that Rosenberg et al uses various percentages of the different polymer matrices to prepare the compositions comprising itraconazole (see Rosenberg et al, examples 1-3, in particular) in order to achieve better solubility and enhanced bioavailability of the antifungal drug at the desired treatment location such as oral cavity. In addition, Baert et al explicitly disclose the preparation of solid dispersion compositions (using the same

procedure or processes such as extrusion, or spray drying, as claimed in the instant invention) suitable for use in gastro-intestinal fluid (such as orally administered or ingested formulations of itraconazole) using HPMC and a derivative of crosslinked polyvinylpyrrolidone in various ratio (that includes HPMC and crosprovidone in a ratio of about 80:20; see Baert et al, page 12, last paragraph and claim 18), thus an artisan of ordinary skill would have had a reasonable expectation of success in optimizing such ratio between polymer combinations as claimed in the instant invention.

2. Claims 1-6 and 8-15 are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over Baert et al (WO 97/44014; IDS) in view of Matsumoto & Zografi (Pharm. Res., 1999; IDS) and Jung et al (WO 99/33467; IDS).

Claims are generally drawn to a solid dispersion (i.e. a composition) comprising a poorly soluble bioactive compound dispersed in a polymeric matrix that comprises a first polymer that allows a homogeneous or molecular dispersion of the bioactive compound in the polymer matrix, and a second polymer that has a dissolution profile associated with the creation of a micro-environment enhancing the dissolution of the bioactive compound in an aqueous environment, wherein said first polymer and said second polymer are present in a ratio of about 70:30 to about 80:20 (see instant claim 1 as amended).

Baert et al (IDS) teach antifungal compositions in the form of solid dispersions having improved bioavailability in an aqueous environment such as gastric fluid (see Baert et al, abstract, page 12-13, examples 1-5, and claims, in particular), wherein the polymer matrix comprises a polymer having a stabilizing effect on the bioactive compound (such as antifungal drug, itraconazole) in solution (see page 4, 2nd paragraph, in particular), wherein the polymer allowing enhanced dissolution of the bioactive compound in an aqueous environment is hydroxypropyl methylcellulose (see

Baert et al, page 12, in particular), wherein the polymer allowing a homogeneous dispersion is crospovidone (a crosslinked polyvinylpyrrolidone, PVP, i.e. a derivative of PVP akin to a copolymer of vinylpyrrolidone and vinylacetate or PVPVA64 as claimed in the instant invention; see Baert et al, page 10, 3rd and last paragraph, in particular), wherein one or more polymer matrices comprise HPMC and crospovidone. The limitations of claims 9 and 10 are explicitly taught by the referenced invention as Baert et al teach solid dispersions comprising polymer matrix that enhance bioavailability of an orally administered bioactive compound, such as a class II drug (see the disclosure provided by the applicants, page 3, lines 16-18 of the instant specification), itraconazole/saperconazole (see Baert et al, page 10, in particular). The limitations of instant claims 14 and 15 (wherein the solid dispersions according to claim 1 are prepared by extrusion or spray drying processes; product by process claims) are also met by the solid dispersions comprising itraconazole and polymer matrices such as HPMC and crospovidone (see Baert, discussion supra) that provide enhanced bioavailability to the antifungal drug when ingested orally.

However, solid dispersions comprising a poorly soluble bioactive compound dispersed in two different polymer matrices such as a copolymer of vinylpyrrolidone and vinylacetate (or PVPVA64) in combination with HPMC, or in combination with Eudragit E100 are not explicitly disclosed by the referenced invention of Baert et al.

Matsumato & Zografi (IDS) disclose the use of polyvinylpyrrolidone derivatives including a copolymer of vinylpyrrolidone and vinylacetate (or PVP/VA64, akin to the crosslinked polymer, crospovidone used by Baert et al, i.e. a functional equivalent) in

the preparation of solid dispersions of indomethacin (a poorly soluble drug in aqueous solutions; see Matsumato & Zografi, page 1722, materials & methods, and conclusions, page 1728, in particular) in order to enhance the solubility and bioavailability of the drug.

Jung et al (IDS) teach method and composition (solid dispersions) of an oral preparation of itraconazole comprising aminoalkyl methacrylate copolymer (i.e. Eudragit E; see abstract, examples 1-7, tables 3-5, and claims, in particular) that is suitable for oral ingestion and antifungal treatment. Jung et al also suggest the use of other polymer matrices in combination with Eudragit, such as crospovidone (as diluent; see Jung et al, page 8, 3rd paragraph, in particular).

It would have been obvious to a person of ordinary skill in the art at the time this invention was made to modify the composition taught by Baert et al (i.e solid dispersions comprising itraconazole comprising two different polymer matrices such as crospovidone and HPMC) such that it comprises of a polymer such as a copolymer of vinylpyrrolidone and vinylacetate (or PVPVA64) as taught by Matsumoto & Zografi, and such that it comprises of a cationic polymer based on dimethylaminoethyl methacrylate and neutral methacrylic esters (such as Eudragit E) as explicitly taught by Jung et al for the preparation of compositions suitable for oral administration and for enhancing the bioavailability in the aqueous environment such as gastro-intestinal tract.

One of ordinary skill in the art would have been motivated at the time of invention to make this kind of modification (i.e. substitution in the polymer matrices, and combinations thereof) in order to obtain suitable solid dispersions with enhanced bioavailability in aqueous environments such as gastric juice or intestinal environment

as suggested by the references with a reasonable expectation of success. Since, all the components of composition (i.e. solid dispersions made by extrusion or spray drying processes) as claimed are taught by the referenced inventions of Baert et al (in combination with the disclosures from Matsumoto & Zografi and Jung et al), the claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the instant claims are properly rejected under 35 U.S.C. § 103(a).

The limitation "wherein said first polymer and said second polymer are present in a ratio of **about 70:30 to about 80:20**, would have been a matter of routine optimization to a person of ordinary skill in the art at the time this invention was made as evident by the fact that Rosenberg et al uses various percentages of the different polymer matrices to prepare the compositions comprising itraconazole (see Rosenberg et al, examples 1-3, in particular) in order to achieve better solubility and enhanced bioavailability of the antifungal drug at the desired treatment location such as oral cavity. In addition, Baert et al explicitly disclose the preparation of solid dispersion compositions (using the same procedure or processes such as extrusion, or spray drying, as claimed in the instant invention) suitable for use in gastro-intestinal fluid (such as orally administered or ingested formulations of itraconazole) using HPMC and a derivative of crosslinked polyvinylpyrrolidone in various ratio (that includes HPMC and crosprovidone in a ratio of about 80:20; see Baert et al, page 12, last paragraph and claim 18), thus an artisan of ordinary skill would have had a reasonable expectation of success in optimizing such ratio between polymer combinations as claimed in the instant invention.

> *"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)*

As per MPEP 2144.06, In order to rely on equivalence as a rationale supporting an obviousness rejection, the ***equivalency must be recognized in the prior art****, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. In re Ruff, 256 F.2d 590, 118 USPQ 340 (CCPA 1958).*

As per MPEP 2144.06, "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be ***useful for the same purpose****, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).*

As per MPEP 2144.05 [R3], II. OPTIMIZATION OF RANGES - A. Optimization Within Prior Art Conditions or Through Routine Experimentation: Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

*As per PPEP 2144.05 (R-3): In the case where the claimed ranges "****overlap or lie inside ranges*** *disclosed by the prior art" a prima facie case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). Similarly, a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are* ***close enough*** *that one skilled in the art would have expected them to have the same properties. Titanium Metals Corp. of America v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). "[A] prior art reference that discloses a range encompassing a* ***somewhat narrower claimed range*** *is sufficient to establish a prima facie case of obviousness." In re Peterson, 315 F.3d 1325, 1330, 65 USPQ2d 1379, 1382-83 (Fed. Cir. 2003).*

Response to Arguments

Applicant's arguments with respect to claims 1-6 and 8-15 (as they pertain to the prior art rejections of record) have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

NO claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyendra K. Singh whose telephone number is 571-272-8790. The examiner can normally be reached on 9-5MF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Satyendra K. Singh
Patent Examiner
Art Unit 1657

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Patent Examiner
Art Unit 1657

SANDRA E. SAUCIER
PRIMARY EXAMINER